

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 5 of 3

**REMARKS**

Claims 30-45 are pending in the subject application. By this amendment applicant has amended claim 30. Applicant maintains that the amendment to the claims raises no issue of new matter. Upon entry of this Amendment claims 30-46 will be pending. Support for the amendment to claim 30 may be found in the specification at, inter alia, page 8, lines 29 to 32; page 9, lines 12-14; page 20, lines 10 and 11; Figs. 7 and 8; and page 19, line 31.

**Claims Rejected Under 35 U.S.C. §103(a)**

**Claims 30-40 and 42-45**

In the October 5, 2007 Office Action, the Examiner rejected claims 30-40 and 42-45 under 35 U.S.C. §103(a) as allegedly obvious over Berger (U.S. Patent No. 6,090,799) in view of Schafer (U.S. Patent No. 4,456,596). The Examiner stated, inter alia, that the "arguments supplied in this Office's Action of 23 March 2007 are hereby incorporated by reference in total." Briefly, the arguments previously set forth by the Examiner are that Berger teaches that "[a]nabolic steroids, as a class, are known to stimulate appetite", and that oxandrolone "increases protein synthesis". The Examiner also stated that Berger teaches that "[i]mproved nutrition is important to individuals with AIDS who have experienced loss of lean body mass". The Examiner further stated that Berger "does not teach the use of anabolic steroids in the treatment of burns." The Examiner asserted that Schafer teaches the use of topically or systemically applied drugs, such as anabolic steroids, for healing processes of tissue lesions such as burns. The Examiner stated that one of ordinary skill in the

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 6 of 3

art would be motivated to combine the teachings of Berger and Schafer because the patents "teach overlapping subject matter, namely treatment using anabolic steroids" and alleged that applicant's invention as claimed is obvious over the combination of references.

The Examiner also stated that applicant's argument is that a *prima facie* case of obviousness has not been established because (1) the references used and the claimed invention treat are directed to different patient populations and weight loss etiologies for these populations are not the same and therefore, there is no demonstrable reasonable expectation of success; (2) Schafer does not explicitly state that anabolic steroids are used systemically to treat burns, but rather, refers to medicinal literature; (3) Berger and Schafer are not combinable, because the technical fields of the two references differ; and (4) there are unexpected results.

In response, applicant respectfully traverses the Examiner's rejection.

*(1) Different Etiologies*

The Examiner has stated that the difference in the etiologies of weight loss in Berger and Schafer is inconsequential. This is not the case, however, for the claimed method recites that the oxandrolone administered is effective for promoting weight gain in a patient suffering weight loss resulting from burn-induced trauma. It is not predictable whether oxandrolone therapy can promote weight gain in a patient resulting from any other type of weight loss. The cited prior art does not, for example, indicate that oxandrolone therapy can promote weight gain in subjects that have not suffered weight loss.

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 7 of 3

Thus, there is no basis for assuming, as the Examiner has done, that the etiology of the weight loss to be treated with oxandrolone is inconsequential. In response to the Examiner's comment that if "it is known in the art that oxandrolone fosters an increase in appetite, then it reasonably follows that the administration of oxandrolone would lead to weight gain", applicant notes that the Examiner's characterization is only "reasonable" if (i) the weight gain is due to increased appetite and (ii) the weight gain due to increased appetite exceeds any weight loss occurring (which is influenced by the etiology). The Examiner has not provided a basis as to why this is the case.

In light of this, applicant repeats the assertion that Berger (patients suffering HIV-associated weight loss) and Schafer (burn victims) each teach different patient populations from the patient population of applicant's invention as claimed (patients suffering from weight loss resulting from burn-induced trauma). The different etiology of weight loss set forth in Berger (HIV-associated myopathy; see col. 1, lines 15-18 and 30-32) compared to the present application (resulting from burn-induced trauma; see page 1, lines 30-33 and page 2, lines 18-20) is not germane to, and does not suggest or teach, even in combination with the teachings of Schafer (which does not discuss weight loss), the invention as claimed. In short, Berger in combination with Schafer neither discuss the subject population recited in the claims nor the recited weight loss to be treated. Consequently, one of ordinary skill in the art would not have an expectation of success in treating weight loss resulting from burn-induced trauma based on the cited art, which neither describes nor suggests the population or pathology as recited in applicant's

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 8 of 3

claims. Applicant maintains that for an obviousness rejection to be proper there must be at least a reasonable expectation of success, but that the cited references provide no suggestion of the claimed treatment or a reasonable expectation of its success.

*(2) Different Use of Steroids*

The Examiner stated that with regard to the Schafer reference, as a matter of law, an issued patent and the references therein are presumed to be valid, and so the reference in Schafer to the medicinal literature to support the premise that topically or systemically applied drugs accelerates the healing processes of physically, chemically, or physiologically induced tissue lesions, including burns, is presumed valid, absent any express evidence to the contrary.

Applicant notes that they have not taken any position that Schafer is not somehow valid. Instead, applicant is pointing out the error in the Examiner's reading of Schafer. Schafer does not state that *anabolic steroids* are used *systemically* to treat burns. To quote, Schafer states: "The use of topically or systemically applied drugs for accelerated healing processes of physically, chemically or physiologically induced tissue lesion, such as burns, surgery or ulcers, is described in the medicinal literature." (see col. 1, lines 10-19). The Examiner is interpreting such a blanket statement to support the position that Schafer *anabolic steroids* are used systemically to treat burns. Schafer does not state that.

Applicant also notes that Schafer goes on to state that "[f]or example, there are reports on anabolic steroids, vitamin A, vitamin K, zinc compounds, silver compounds or serum factors,

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 9 of 3

e.g. factor XIII in blood coagulation, or high molecular compounds such as collagen or cartilage which all accelerate the healing process of tissue injuries." In short, Schafer nowhere actually states that anabolic steroids are given systemically. Applicant thus maintains that Schafer, taken in combination with Berger, does not teach or suggest systemic administration of oxandrolone (e.g. orally or injected as recited in applicant's claim 46) to treat weight loss resulting from burn-induced trauma.

(3) *Unexpected results*

The Examiner asserted that the fact that specification teaches that even with the same calorific intake, a dramatically increased weight gain is seen in patients treated with oxandrolone is not in and of itself suggestive of unexpected results, because calorific intake alone does not contribute, exclusively to weight gain.

Applicant notes that the Examiner's statement does nothing to diminish applicant's position that the weight gain is unexpected, absent an indication as to what would be expected. Applicant respectfully requests that the Examiner state why one would expect to see the results set forth in the specification of up to double the weight gain (see page 20, lines 10 and 11; and Figs. 7 and 8, group I compared to group II) in subjects treated with oxandrolone compared to subjects not administered oxandrolone but having almost identical caloric intake (of which the protein intake was "identical", see page 19, line 31). Applicant maintains that the present application discloses an unexpectedly high weight gain. Berger in combination with Schafer does not anywhere suggest such an outcome.

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 10 of 3

#### **Claims 30 and 41**

The Examiner also rejected claims 30 and 41 under 35 U.S.C. §103(a) as allegedly obvious over Berger, as cited, in view of Schafer, as cited, and in further view of Labrie et al. (U.S. Patent No. 5,434,146). The Examiner stated, inter alia, that the "arguments supplied in this Office's Action of 23 March 2007 are hereby incorporated by reference in total." Briefly, the arguments previously set forth by the Examiner are that Berger does not teach the administration of oxandrolone in a sustained release formulation but that Labrie et al. teach the administration of oxandrolone in a sustained release formulation. The Examiner alleged that in view of this it would have been prima facie obvious to one of ordinary skill in the art that the administration of an effective amount of oxandrolone in a sustained release formulation would be effective for promoting weight gain after weight loss resulting from burn-induced trauma. The Examiner further stated that applicant argues that neither Berger or Labrie et al. teach a sustained release formulation for oxandrolone. The Examiner asserted, however, that Labrie et al. do teach the sustained release of oxandrolone, citing Abstract, col. 21, lines 17 and 61-68 and col. 23, lines 20-24).

Applicant notes that, as set forth hereinabove, there is no teaching of the method of claim 30 in the combination of Berger and Schafer, and Labrie et al. does not cure this deficiency, nor does the Examiner suggest that it does. In fact Labrie et al. does not teach weight gain therapies or subjects that have experienced a burn, but instead teaches treatment and prevention of estrogen-related diseases (see Abstract and Summary of Invention). The Examiner does assert

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 11 of 3

that the Labrie et al. discloses administration of oxandrolone in a sustained release formulation. To the extent that Labrie et al. may teach a sustained release composition, it still does not teach a method of administration of oxandrolone to a patient for treating weight loss resulting from burn-induced trauma, nor does it cure the other deficiencies of the combination of Berger and Schafer. Applicant maintains that the cited combined references do not teach or make obvious applicant's invention as claimed.

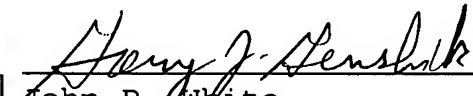
Thus, applicant maintains that claims 30-47 as amended are not obvious over the combination of cited references. Accordingly, applicant respectfully requests that the Examiner reconsider and withdraw this ground of rejection.

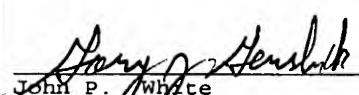
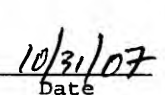
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

Applicant : Don Fishbein  
Serial No. : 10/799,264  
Filed : March 12, 2004  
Page 12 of 3

No fee, other than the enclosed \$405.00 RCE fee, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully Submitted,

  
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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	
 John P. White Reg. No. 28,678 Gary J. Gershik Reg. No. 39,992	 Date